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| 10/589,211 | 08/11/2006 | Philip M. Sher | AL2006-012 | 7154 |

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ALTIMATIA, L.L.C.
16 ELM RIDGE ROAD
PENNINGTON, NJ 08534

| EXAMINER | |
|---|---|
| D'ANGELO, MICHAEL J | |
| ART UNIT | PAPER NUMBER |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/589,211 | SHER, PHILIP M. | |
| | Examiner | Art Unit | |
| | MICHAEL D'ANGELO | 3735 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *30 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

### *Response to Amendment*

Receipt is acknowledged of applicant's amendment filed on April 30th, 2009. Claims 1-36 are pending and an action on the merits is as follows.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-4, 7-16, 19-28 and 31-36 rejected under 35 U.S.C. 103(a) as being unpatentable over Saidara et al. (US 2005/0038332) in view of Shin et al. (US 2005/0004439).

**Regarding claim 1,** Saidara discloses a system configured to continuously receive data from blood glucose monitoring sensors (paragraph 61, line 3), the system configured to convert sensor data into current glucose concentration values (paragraph 15, lines 1-6), the system configured to support fluctuating blood glucose notification threshold profiles (paragraph 90, lines 14-23), the profiles comprising an upper and lower concentration threshold function (paragraph 91, lines 1-3); the threshold functions comprising specific values at specific times (paragraph 119); the system configured to compare a current glucose concentration value with an upper and lower threshold value (paragraph 90, lines 14-16); the system configured to alert a user when the current glucose concentration value is greater than an upper threshold and lower than a lower threshold (paragraph 91, lines 5-13), but fails to disclose a continuously fluctuating threshold profile.

However Shin, discloses the use of a continuously fluctuating threshold profile (paragraphs 21 and 163, the examiner notes that if the threshold can vary based upon the current glucose level it will continuously fluctuate along with a changing glucose concentration).

5. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the physiological monitor of Saidara with using a continuously fluctuating threshold in order to provide a dynamic means for removing glucose values that would then produce the most accurate glucose sensor data.

**Regarding claim 13,** Saidara discloses defining a fluctuating blood glucose notification threshold profile (paragraph 90, lines 14-23); the profile comprising an upper and lower concentration threshold function (paragraph 91, lines 1-3), the upper and lower threshold functions forming the bounds of an expected concentration range (paragraph 91, lines 1-3), the threshold functions comprising specific values at specific times (paragraph 119); activating the threshold profile (paragraph 92); continuously receiving data from the monitoring sensors (paragraph 61, line 3); converting sensor data into current glucose concentration values paragraph 15, lines 1-6); comparing a current glucose concentration value with an upper and lower threshold value (paragraph 90, lines 14-16); and alerting a user when the current glucose concentration value is greater than an upper threshold and lower than a lower threshold (paragraph 91, lines 5-13), but fails to disclose the use of a continuously fluctuating threshold profile.

However Shin, discloses the use of a continuously fluctuating threshold profile (paragraphs 21 and 163, the examiner notes that if the threshold can vary based upon the current glucose level it will continuously fluctuate along with a changing glucose concentration).

6. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the physiological monitor of Saidara with using a continuously

fluctuating threshold in order to provide a dynamic means for removing glucose values that would then produce the most accurate glucose sensor data.

**Regarding claim 25,** Saidara discloses a computer readable medium comprising executable processor code (paragraph 68), the code comprising code for receiving data from continuous blood glucose monitoring sensors (paragraph 94); code for converting blood glucose sensor data into current blood glucose concentration values (paragraph 94); code supporting blood glucose notification threshold profiles, the threshold profiles comprising (paragraph 94): an upper blood glucose concentration threshold function (paragraph 94) and a lower blood glucose concentration threshold function (paragraph 94), the threshold functions comprising specific values at specific times (paragraph 119); code for comparing a current blood glucose concentration value with a corresponding upper blood glucose concentration threshold value (paragraph 94); code for comparing a current blood glucose concentration value with a corresponding lower blood glucose concentration threshold value (paragraph 94); code for alerting a user when a current blood glucose concentration is greater than a corresponding upper blood glucose concentration threshold value (paragraph 91, lines 11-13 and paragraph 94); and code for alerting a user when a current blood glucose concentration is less than a corresponding lower blood glucose concentration threshold value (paragraph 91, lines 11-13 and paragraph 94), but fails to disclose code supporting a continuously fluctuating threshold profile.

However Shin, discloses the use of a continuously fluctuating threshold profile (paragraphs 21 and 163, it is inherent that if the system of Shin uses a fluctuating profile

its processor must have a supporting code as well, the examiner notes that if the threshold can vary based upon the current glucose level it will continuously fluctuate along with a changing glucose concentration).

7. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the physiological monitor of Saidara with using a continuously fluctuating threshold in order to provide a dynamic means for removing glucose values that would then produce the most accurate glucose sensor data.

**Regarding claims 2 and 14,** Saidara discloses alerting a user when a rate of change of a current blood glucose concentration exceeds a threshold rate of change (paragraph 90, lines 14-23).

**Regarding claims 3, 15 and 27,** Saidara discloses an alert comprising one or more of a visual, auditory, and tactile alert (paragraph 117, lines 13-15).

**Regarding claims 4, 16 and 28,** Saidara discloses a graphical display displaying a graph of measured blood glucose concentration and a code supporting such (view figure 8B, paragraph 54).

**Regarding claim 7, 19, and 31,** Saidara discloses a data store configured to support storage and retrieval of blood glucose data and the steps/code of/for storing blood glucose data in the store and retrieving the data from the store (paragraph 30, lines 6-20).

**Regarding claims 8, 20 and 32,** Saidara discloses the data are labeled (paragraph 31, lines 1-10).

**Regarding claims 9, 21, and 33,** Saidara discloses allowing a user to define a blood glucose threshold profile by using the step of retrieving a blood glucose threshold profile from a data store and modifying it (paragraph 92 and 93).

**Regarding claim 10, 22, and 34,** Saidara discloses allowing a user to define a blood glucose threshold profile by the system allowing the user to select a blood glucose related data item (paragraph 93).

**Regarding claims 11, 23, and 35,** Saidara discloses allowing a user to define a blood glucose threshold profile by a method of entering numeric data defining an upper or lower concentration threshold (paragraph 104 and 105).

**Regarding claims 12, 24, and 36,** Saidara discloses the profile is from about 1-12 hours (paragraph 100, lines 1-17).

**Regarding claim 26,** Saidara discloses code configured to alert a user when a rate of change of a current blood glucose concentration exceeds a threshold rate of change (paragraph 94).

8. Claims 5-6, 17-18, and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saidara et al. (US 2005/0038332) in view of Shin et al. (US 2005/0004439) and further in view of Glukhovsky et al (US 7,200,253).

**Regarding claim 5 and 17 and 29,** Saidara as modified by Shin discloses graphs of an upper and lower concentration threshold are displayed in different colors while a measured value is in a third color (view figure 8E, high and low regions as well as the black line of Saidara), and further discloses an indication using multiple colors

(paragraph 185 of Saidara), but fails to distinctly disclose each parameter corresponding to a color.

However, Glukhovsky et al. discloses marking sections (or concentration functions) with a color based on a threshold.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify a graphing system similar to that of Saidara, as modified by Shin, to incorporate having each concentration function a specific color as taught by Glukhovsky in order to allow for easy viewing of the functions over time.

**Regarding claims 6, 18 and 30,** Saidara discloses the first and second colors are the same (view figure 4A).

### *Response to Arguments*

9. Applicant's arguments, see page 1, filed April 30th, with respect to the rejection(s) of claim(s) 1-4, 7-16, 19-28 and 31-36 under 35 U.S.C 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Saidara and Shin as disclosed above. The failure of Saidara disclosing a continually fluctuating threshold has been remedied by the addition of Shin which now makes the arguments regarding all the independent claims and the combination of Saidara and Glukhovsky moot.

### *Conclusion*

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See US form 892-Notice of References Cited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL D'ANGELO whose telephone number is (571) 270-7112. The examiner can normally be reached on Monday-friday 9-5 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/MD/
Examiner, Art Unit 4185